



SAFETY DATA SHEET

1. Identification

Product identifier	Atorvastatin Calcium	
Other means of identification		
Catalog number	1044516	
CAS number	344423-98-9	
Chemical name	Calcium (β R, δ R)-2-(p-fluorophenyl)- β , δ -dihydroxy-5-isopropyl-3-phenyl-4-(phenylcarbamoyl) pyrrole-1-heptanoate (1:2) trihydrate	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2B
	Reproductive toxicity	Category 1B
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger	
Hazard statement	Causes eye irritation. May damage fertility or the unborn child.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.	

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Atorvastatin Calcium		344423-98-9	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of statin overdose may include the following: Administer activated charcoal as an aqueous slurry. For rhabdomyolysis, administer 0.9% saline to maintain urine output of 2 - 3 milliliters/kg/hour. Monitor fluid balance, serum electrolytes, CPK, liver enzymes, and renal function. Administer diuretics if needed to maintain urine output. Urinary alkalinization is not recommended. Hemodialysis is not expected to enhance clearance.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO ₂ . Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

Exposure limit values

Industrial Use Material	Type	Value
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Atorvastatin Calcium (CAS 344423-98-9)	TWA	50 micrograms/m3
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Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Crystalline powder.

Color

White. Off-white.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

312.8 °F (156 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Solubility (other) Acetonitrile: Very slightly soluble.
Ethanol: Slightly soluble.
Methanol: Freely soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Statin.

Dust explosion properties

Kst 65 bar.m/s

St class Weak explosion.

Minimum ignition energy (MIE) - dust cloud 50 - 100 mJ

Molecular formula (C33H34FN2O5)2 . Ca . 3H2O

Molecular weight 1209.41 g/mol

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Acids. Bases. Oxidizing agents.

Hazardous decomposition products Ca. F-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information**Information on likely routes of exposure**

Inhalation Knowledge about health hazard is incomplete.

Skin contact Knowledge about health hazard is incomplete.

Eye contact Causes eye irritation.

Ingestion Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and toxicological characteristics Statins: Muscle pain or weakness. Mood or mental changes. Memory loss and confusion. Skin rash. Gastrointestinal disturbances. Hyperglycemia.

Information on toxicological effects**Acute toxicity**

Product	Species	Test Results
Atorvastatin Calcium (CAS 344423-98-9)		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Mouse	> 5000 mg/kg
	Rat	> 5000 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes eye irritation.	
Local effects		
Irritation test		
Result: Irritant.		
Species: Rabbit		
Organ: Eye.		
Severity: Mild.		
Irritation test		
Result: Not irritating.		
Species: Rabbit		
Organ: Skin.		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about sensitization hazard is incomplete.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Sensitization		
Result: Not sensitizing.		
Species: Guinea pig		
Organ: Skin.		
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Ames test (E. coli)		
Result: Negative.		
Ames test (Salmonella typhimurium)		
Result: Negative.		
Mutagenicity: Chromosomal aberrations in lung cells		
Result: Negative.		
Species: Hamster, Chinese		
Mutagenicity: HGPRT forward mutation assay in lung cells		
Result: Negative.		
Species: Hamster, Chinese		
Carcinogenicity	Based on available data, the classification criteria are not met.	
> 100 mg/kg/day Carcinogenicity		
Result: Two rare tumors in high-dose females.		
Species: Rat		
Test Duration: 2 years		
> 400 mg/kg/day Carcinogenicity		
Result: Increase in liver adenomas in high-dose males and liver carcinomas in high-dose females.		
Species: Mouse		
Test Duration: 2 years		
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	May damage fertility or the unborn child. Therapeutic use of statins during pregnancy may decrease cholesterol and cholesterol-derived substances essential for fetal development. Results of animal studies indicate that many statins are associated with adverse fetal outcomes at maternally toxic doses.	

Reproductivity

- > 175 mg/kg/day Reproductivity study
Result: Did not impair fertility in female rats.
Species: Rat
- > 225 mg/kg/day Reproductivity study
Result: Decreased pup survival, decreased body weight, and delayed pup development.
Species: Rat
- > 225 mg/kg/day Reproductivity study
Result: Did not impair fertility in male rats.
Species: Rat
- > 300 mg/kg/day Reproductivity study
Result: No birth defects.
Species: Rabbit

Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.
Aspiration hazard	Based on available data, the classification criteria are not met.
Further information	Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA. This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes**Classified hazard categories** Combustible dust
Serious eye damage or eye irritation
Reproductive toxicity**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	02-02-2009
Revision date	01-17-2019
Version #	04
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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